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Purdue et al. v. Endo et al.
Nos. 00 Civ. 8029 (SHS);
01 Civ. 2109 (SHS); 01 Civ. 8177 (SHS)

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CONFIDENTIAL INFORMATION
Purdue v. Boehringer

Trial Exhibit

Purdue et al. v. Endo et al.
Nos. 00 Civ. 8029 (SHS);
01 Civ. 2109 (SHS); 01 Civ. 8177 (SHS)

DX 3739

P 054891

memo

RECEIVED

MAY - 4 1994

to OxyContin Project Team

from R. Reder R. Goldenheim, MD

dept Medical

subject OxyContin™ Tablets Investigator Survey
Preliminary Report

date May 3, 1994

Attached please find the results of the survey Ron and I recently sent to ten of our "high volume" OxyContin investigators. The results should help us understand how cancer specialists are beginning to view OxyContin™. This information may assist focus group testing.

SUMMARY

Ten OxyContin™ Tablets investigators treating cancer patients were surveyed during the first quarter of 1994. Eleven responses were received; the responses were anonymous. The purpose of the questionnaire was to collect impressions of OxyContin™ Tablets. Because they are actually using the drug, the investigators' comments are important as an early indication of where the product is being positioned in their armamentarium.

The investigators most often used MS Contin® (9/11) as their leading oral, opioid medication. The investigators rated OxyContin™ Tablets as useful and effective and would often use the product if commercially available. However, these positions were not held by all.

The oral morphine to oral oxycodone conversion ratio was most often felt to be 1:1.

OxyContin™ benefits included the following:

- easier titration than Duragesic (but not MS Contin® or oxycodone IR)
- dependable efficacy
- q12h dosing
- use of oxycodone for both malignant and non-malignant pain
- use of oxycodone on steps 2 and 3 of the analgesic ladder
- improved compliance
- independent titration of APAP/NSAID
- uninterrupted sleep

It was not strongly felt that OxyContin™ would decrease hospitalization, concomitant medication, office visits or phone calls.

Generally, the side effect profile was considered the same as other opioids.

The majority of investigators felt that their patients found OxyContin™ helpful, improved their quality of life and was more acceptable than morphine (in terms of morphine "stigma").

RR:msd
attachment

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Purdue v. Boehringer

P 054892

OxyContin™ Tablets Investigators' Survey
May, 1994
R. Reder, M.D., R. Fitzmartin, Ph.D.

During the spring of 1994 we mailed a survey to ten of our OxyContin™ investigators (Appendix I). All had experience using OxyContin™ tablets under IND #29,038. Eleven responses were received. The responses were anonymous. The following is a tabulation of those data.

In answer to the question (3a) as to which oral medications are used most often in pain management, 9/11 said MS Contin® is used most often, 1/11 said NSAIDS were used most often and 1/11 said Percocet. Hydromorphone (4/11), MSIR (4/11) and Percocet (3/11) were the second most commonly used opioid drugs.

Most questions were designed to gain insight into the impression these investigators held of OxyContin™. The answer to a question rating usefulness (Question 1; 1 = least useful; 5 = extremely useful) was 4.0 (range 2 to 5). In the matter of ranking the use of OxyContin™ tablets if commercially available (Question 3b; 1 = most often used; 4 = least often used), the investigators answered an average of 2.1 (range 1 to 3). When asked to rate OxyContin™'s effectiveness (Question 6; 1 = minimally effective; 5 = highly effective), the answer was 4.0 (range 2-5).

In terms of the conversion of oral morphine to oral oxycodone, the equivalence ratio was considered to be 0.5 (1/11), 1.0 (7/11), 2 (1/11), 5 (2/11) (Question 5).

The investigators were asked several questions about possible benefits of OxyContin™. In question 2, 10/11 felt OxyContin™ was easier to titrate than Duragesic; 0/11 felt it was easier than MS Contin® and 1/11 felt it was easier than oxycodone IR tablets. 7/11 felt OxyContin™ had dependable efficacy. 11/11 felt q12h dosing was a benefit. 5/11 felt the presence of oxycodone on the WHO ladder in steps 2 and 3 was a benefit. 7/10 reported the use of oxycodone in both malignant and non-malignant pain was a benefit. Improved compliance (9/11), independent titration of NSAID and opioid (8/11) and uninterrupted sleep (6/11) were considered benefits. The numbers of investigators who felt OxyContin™ would decrease hospitalizations were 2/11, concomitant medication use 3/11, office visits 3/11, and phone calls 3/11 (question 4).

In terms of side effects, the investigators felt that compared at equianalgesic doses OxyContin™ would have less side effects than Dilaudid (2/11), MS Contin® (3/11), Duragesic (2/11) and Oxycodone IR (3/11) (question 2). The side effects seen during treatment (question 7) were no comment (2/10) and various comments on side effects similar to other narcotics.

The final group of questions were patient centered. In answer to whether OxyContin™ increased their patients' quality of life 7/11 said yes (question 4). 9/11 investigators said their patients found OxyContin™ tablets helpful (question 8). The average feeling regarding enhancement of their patients' quality of life (question 9; 1 = strongly disagree; 5 = strongly agree) was 3.4 (range 1-5). The final question was asked about morphine "stigma". When asked if they felt OxyContin™ would be more acceptable to their patients from the investigators' point of view, 7/11 said yes; from their patients' point of view, 11/11 said yes.

004

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Purdue v. Boehringer

P 054893

Quotations:

"This is a great drug. I am looking forward to using it more."

"Patients report easier to use because of less frequent dosing."

"Less nausea and vomiting. Drowsiness is of shorter duration."

"Apart from occasional (but severe) nausea and vomiting it is an excellent analgesic for cancer patients."

"Patient acceptance was not good."

"The benefits were outstanding and the side effects were limited."

"Works well for mild to moderate pain. Works not as well for severe pain."

004
May 3, 1994
[msd]

2

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Purdue v. Boehringer

P 054894

OxyContin™ Tablets Clinical Experience Questionnaire

Your experience with OxyContin™ is important to me.
Please take a few minutes to complete this opinion survey.

Thanks. Bob Roder

1. Please rate the usefulness of OxyContin™ Tablets in your therapeutic armamentarium for the treatment of chronic pain.

1 = Least useful, 5 = Extremely useful

1 2 3 4 5

Comment: _____

2. Which of the following are benefits you've seen of OxyContin™ Tablets (check all that apply).

Easier to titrate than:

- ☐ Duragesic Patches
☐ MS Contin Tablets
☐ Oxycodone immediate-release tablets

Dependable efficacy

- ☐ Q12h dosing
☐ Included in both steps 2 and 3 of the WHO analgesic "ladder"
☐ Oxycodone's accepted use in both chronic malignant and non-malignant pain

Less side effects than equianalgesic doses of:

- ☐ Dilaudid Tablets
☐ MS Contin Tablets
☐ Duragesic Patches
☐ Oxycodone immediate-release tablets
☐ Improved compliance
☐ Independent titration of OxyContin and NSAID
☐ Uninterrupted nighttime sleep comparable to MS Contin tablets or other long-acting opioids
☐ Other (specify) _____
☐ None of the above

3. a) Please rank the four leading oral medications you use for pain management; 1 = most often used and 4 = least often used.

☐ NSAIDs, (specify) _____

- ☐ Acetaminophen (Tylenol)
☐ Acetaminophen w/codeine 30 mg (Tylenol #3)
☐ Hydrocodone/APAP (Vicodin)
☐ Oxycodone w/aspirin (Percodan)
☐ Oxycodone w/acetaminophen (Percocet)
☐ Immediate-release morphine (MSIR)
☐ Controlled-release morphine (MS Contin)
☐ Hydromorphone (Dilaudid)
☐ Other (specify) _____

005

CONFIDENTIAL INFORMATION
Purdue v. Boehringer

P 054895

3. b) How would you rank OxyContin™ Tablets if it was commercially available?
(1 = most often used and 4 = least often used)

1 2 3 4

4. Please indicate in which areas OxyContin™ Tablets may have resulted in changes (check all that apply).

	<u>Increase</u>	<u>Decrease</u>
Concomitant medication use	<input type="checkbox"/>	<input type="checkbox"/>
Hospitalizations	<input type="checkbox"/>	<input type="checkbox"/>
Office visits	<input type="checkbox"/>	<input type="checkbox"/>
Telephone calls to the office	<input type="checkbox"/>	<input type="checkbox"/>
Quality of life	<input type="checkbox"/>	<input type="checkbox"/>
Other (specify) _____		

5. In your experience, how many milligrams (mg) of oral morphine is equivalent to one (1) milligram of oxycodone, alone, i.e., without acetaminophen or aspirin?

mg

6. How would you rate the effectiveness of OxyContin™ Tablets q12h?

1 = Minimally effective, 5 = Highly effective

1 2 3 4 5

7. What side effects do you see with OxyContin™ Tablets?
